DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Cryomedical Sciences, Inc.
c/o Mr. E. J. Smith
Smith Associates
P.O. Box 4341
Crofton, Maryland 21114

Re: K011073
Trade/Device Name: CryoPlan System
Regulation Number: 878.4350
Regulatory Class: II
Product Code: GEH
Dated: July 25, 2001
Received: July 26, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K011073

Device Name: CryoPlan System

Classification Panel: GEH 21 CFR 878.4350

Indications for Use:

for Mark N Milham
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011073

The CryoPlan Cryotherapy Treatment Planning System is intended for use in general surgery, urology, gynecology, oncology, neurology, thoracic surgery, dermatology, ENT, and proctology. The system provides a visualization and monitoring tool used to assist physicians/clinicians in:

- (Pre) Planning: Provide tools to allow the physician to capture images during Volume Study Procedure and then create a cryosurgery plan to treat the patient. Provide the capability to visualize in 2D and 3D a simulated execution of the cryosurgical plan over time.
- OR Monitoring: Monitoring of the freezing process by detection of the ice front in the live images as it approaches critical structures. Display of live thermocouple data to provide additional temperature feedback for the surgeon.
- Post Procedure Quality Assurance: Highlighting discrepancies by a comparison of the actual event log with that of the planned event log.

The CryoPlan is indicated for the following uses:

Urology
- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia.

Oncology
- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Dermatology
- Ablation or freezing of skin cancers and other cutaneous disorders

Gynecology
- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

General Surgery
- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin

- Ablation of luekoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemanglomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemanglomas, recurrent cancerous lesions.

Thoracic Surgery

- Ablation of arrhythmic cardiac tissue
- Ablation of cancerous lesions

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ Over-the-Counter Use: _____

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011073